Citation:

Epstein LH, Paluch RA, Beecher MD, Roemmich JN. Increasing healthy eating vs. reducing high energy-dense foods to treat pediatric obesity. *Obesity (Silver Spring)*. 2008;16(2):318-26.

PubMed ID: 18239639

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare targeting increased eating of healthy foods vs. reducing intake of high energy-dense foods within the context of a family-based behavioral weight control program.

Inclusion Criteria:

- Children between 8 and 12 years of age
- Over the 85th BMI percentile
- Not taking any weight altering drugs
- Reading at or above a third grade level
- One parent willing to attend treatment meetings
- No family member participating in an alternative weight control program
- No children or parents having current dietary or exercise restrictions or psychiatric problems.

Exclusion Criteria:

- Taking any weight altering drugs
- Family member participating in an alternative weight control program
- Children or parents having current dietary or exercise restrictions or psychiatric problems.

Description of Study Protocol:

Recruitment

- Participants were recruited through newspaper advertisements, posters, flyers, television interviews, direct mailings, and personal and physician referrals.
- Screening was conducted on 105 families, with 41 families randomized into one of two treatment groups: reducing high-fat, high-sugar foods group, or increasing healthy (fruit, vegetable, and low-fat dairy) foods group.

- Eighteen families who met criteria declined to participate.

Design: Randomized controlled trial

- Forty-one, 8-12 year-old children >85th BMI percentile were randomly assigned to a 24-month family-based behavioral treatment that targeted increasing fruits and vegetables and low-fat dairy vs. reducing intake of high energy-dense foods.
- Families were studied in two cohorts, with all families participating in each cohort screened before randomization, and randomization of all families who met criteria for each cohort was implemented using a random number algorithm stratifying by gender.
- Accepted families attended weekly meetings for 2 months, biweekly meetings for 2 months, and one monthly meeting, followed by assessment meetings at 6-month, 1-year and 2-year time points.
- Height and weight and all dependent measures were collected at baseline, 6, 12, and 24 months.

- Both groups were given the Traffic Light Diet to reduce their daily energy intake, and a similar activity program. Each group received reinforcement for meeting their dietary goals through a point system. These points were calculated based on the participant's recording in a daily food journal.

Blinding used (if applicable) Not reported

Intervention (if applicable)

- Randomized into one of two treatment groups: reducing high fat, high sugar foods group or increasing healthy (fruit, vegetable and low fat dairy) foods group.

Statistical Analysis

- T-tests and chi-square were used to detect between-group differences at baseline. Group differences in zBMI, eating and activity behaviors, child feeding, and parenting were assessed using mixed effects regression (MRM) models.
- The models included a random intercept, months as a time variant level 1 predictor, and group and child age, gender, socioeconomic status, and baseline values as time invariant level 2 predictors for all but the zBMI model, where just socioeconomic status was a level 2 predictor, as zBMI values are standardized for child age and gender.
- Linear and quadratic months effects were included. Significant group by time interactions were tested by additional MRM models to compare between group differences from baseline to 6, 12, and 24 months.

Data Collection Summary:

Timing of Measurements

- Accepted families attended weekly meetings for 2 months, biweekly meetings for 2 months, and one monthly meeting, followed by assessment meetings at 6-month, 1-year and 2-year time points.
- Height and weight and all dependent measures were collected at baseline, 6, 12, and 24 months.

Dependent Variables

- zBMI of children and parents
- Eating and activity behaviors
- Child feeding
- Parenting

Independent Variables

- Random assignment to a 24-month family-based behavioral treatment that targeted increasing fruits and vegetables and low-fat dairy vs. reducing intake of high energy-dense foods.
- Both groups were given the Traffic Light Diet to reduce their daily energy intake, and a similar activity program. Each group received reinforcement for meeting their dietary goals through a point system. These points were calculated based on the participant's recording in a daily food journal.

Control Variables

- Child age
- Gender
- Socioeconomic status
- Baseline values

Description of Actual Data Sample:

Initial N: 105 families. 41 families were randomized.

Attrition (final N): 27 families (14 in the Increase Healthy Food Group and 13 in the Reduce High Energy Dense Foods Group).

Age: 8-12 y

Ethnicity: 6 (15%) were minority families.

Other relevant demographics:

Anthropometrics

There were no statistically significant differences between groups at baseline.

Location: New York

Summary of Results:

Key Findings

- Children in the increase healthy food group showed greater reduction in zBMI compared to children in the reduce high energy-dense food group at 12- (−0.30 zBMI units vs. −0.15 zBMI units, $P = 0.01$) and 24- (−0.36 zBMI units vs −0.13 zBMI units, $P = 0.04$) month follow-up.
- Parents in the increase healthy food group showed greater reductions in concern about child weight ($P = 0.007$), and these changes were associated with child zBMI change ($P = 0.008$).
- Children in the reduce high energy-dense group showed larger sustained reductions in high energy-dense foods ($P < 0.05$).
- Baseline levels of high energy-dense foods ($P < 0.05$), parent food restraint ($P = 0.01$), parent concern over parent weight ($P = 0.01$) and parent acceptance of the child ($P < 0.05$) moderated child zBMI change, with greater sustained reductions in zBMI for children in the increase healthy food group for each measure.
- Parent zBMI change followed the same pattern as child changes, and parent and child zBMI changes were correlated ($P < 0.001$).

Other Findings

- No group differences were observed in any of the child or parent characteristics, with the exception of child perceptions of maternal acceptance and paternal autonomous control, which were higher in the decrease high energy-dense food group.
- Six (15%) were minority families.
- The MRM to predict changes in zBMI showed a linear interaction of group by months ($P < 0.01$), as the increase healthy food group showed greater reductions over time in comparison to the reduce high energy-dense food group.
- Significant reductions in zBMI were also observed over time ($P < 0.001$), with overall reductions at 6 ($P < 0.001$) and 12 ($P = 0.037$) months.
- RED foods showed a significant quadratic change over time by groups ($P < 0.05$).
- Changes over time were also observed for RED foods, with significant decreases from baseline to 6 ($P < 0.001$), 12 ($P < 0.001$) and 24 ($P < 0.001$) months. No significant changes in low-fat dairy were observed.
- A significant linear interaction of group by time was observed for parent concern for child weight ($P = 0.007$), with greater sustained reductions in parent concern for parents in the increase healthy food group.
- Significant between group differences in parent concern for child weight were observed at 24 months ($P = 0.03$).
- Significant overall reductions in parent concern across both groups were observed ($P = 0.001$), with significant reductions from baseline to 6 ($P < 0.001$), 12 ($P = 0.004$) and 24 ($P = 0.002$).
- In mediational analyses, parent concern for child weight interacted with group to predict zBMI change over time ($P = 0.008$).
- There were significant reductions over time in parent concern for child weight ($P < 0.001$), perceived responsibility for child weight ($P = 0.004$); parent restraint over child eating ($P = 0.001$) and monitoring of child behavior ($P = 0.03$).
- Baseline levels of zBMI ($P = 0.017$), gender ($P = 0.014$), and age $P = 0.006$) interacted with treatment to influence success.
- Children with lower baseline zBMI values, older children and girls assigned to the increase healthy food group showed greater sustained reductions in zBMI over the 2 years than children assigned to the reduce high energy-dense food group.
- The experimental treatment to increase healthy foods improved zBMI changes for children who consumed higher levels of RED foods at baseline. MRM models showed that parent zBMI values over 2 years were correlated with child zBMI values ($P < 0.001$).
- zBMI changes from baseline between the increase healthy food and reduce high energy-dense food groups. Mixed effects regression models showed an interaction of group by months ($P = 0.03$). Significant between group differences were observed at 12 months ($P = 0.01$) and 24 months ($P = 0.04$).

- Mixed effects regression models showed significant differences by group in RED foods ($P < 0.05$), with significant differences being observed at 24 months ($P = 0.03$). Mixed effects regression models showed significant differences by group in parent concern over child weight $P = 0.008$), with significant differences being observed at 24 months ($P = 0.03$).
- Mixed effects regression models showed that baseline levels of RED foods ($P < 0.05$) interacted with treatment to influence outcome. The effects of the treatments were greater for children who had higher levels of baseline consumption for RED foods.
- Mixed effects regression models showed that baseline levels of restriction ($P = 0.011$), concern over parent weight ($P = 0.009$), and child reported parent acceptance ($P = 0.045$) interacted with treatment to influence outcome.
- In each interaction, children randomized to the increase healthy food group showed better long-term change than children randomized to reduce high energy dense food group for children with high levels of the moderating variable.

Author Conclusion:

In summary, we have shown that increasing healthy eating may be an important target in pediatric weight control programs, and these changes may enhance weight loss. However, additional research is needed to understand the mechanisms for these changes. A primary goal should be to use more sensitive measures of dietary change to track changes in healthy eating vs. reductions in eating less healthy foods. Finally, parents in the healthy food group may make important changes in purchasing and food storage that could influence child intake. Families in the increase healthy food group may be purchasing more healthy foods than families in the reduce high energy-dense food group, while both groups of families may be reducing purchasing and cooking high energy-dense foods. This change in stimulus control, by increasing the variety and access to healthy foods may be responsible in part for changing child eating. It is possible that these factors are not working independently, but may interact. Children may find it easier to substitute healthy foods for less healthy foods if there is a greater variety of healthy foods to eat and access to less healthy alternatives is reduced.

Reviewer Comments:

- *This is a well designed randomized controlled trial. Study results suggest that the healthy foods had a significant effect on BMI.*
- *The duration of the study also supports the association of weight management and healthy diet and life style in children.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes

1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes

7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes